

ATTACHMENT 1

In re National Prescription Opiate Litigation: MDL 2804
Summary Sheet of Concise Issues Raised

Opposition Name: Plaintiffs' Consolidated Memorandum in Opposition to Defendants' Motions for Summary Judgment on Proof of Causation (Dkt. #s 1869, 1897, 1941)

Opposing Parties: Plaintiffs Summit and Cuyahoga Counties

Issue 1: Have Plaintiffs produced evidence that Defendants' rampant unlawful conduct was a factual cause of the extensive opioid-related harms Plaintiffs have suffered?

Answer: Yes. When multiple wrongdoers contribute to a combined harm, the plaintiffs must show that each defendant's conduct was a substantial factor in producing the harm. *Iron Workers Local Union No. 17 Ins. Fund v. Philip Morris, Inc.*, 29 F. Supp. 2d 801, 821-22 (N.D. Ohio 1998); *Pang v. Minch*, 559 N.E.2d 1313, 1324 (Ohio 1990).

Here, Plaintiffs Summit and Cuyahoga Counties produce a trove of evidence showing that Defendants engaged in an illegal and deceptive marketing campaign that changed prescribing practices towards over-prescription of opioids, while they also failed to prevent diversion of these deadly drugs to unauthorized uses. This unlawful conduct created an excess supply of prescription opioids, which caused extensive public health and social harms related to both licit and illicit opioid use that have cost and will continue to cost the Plaintiff Counties hundreds of millions of dollars to address.

The evidence that the Manufacturer Defendants' illegal and deceptive promotion conduct caused these harms includes:

- the conduct itself, from which a jury can infer that the Manufacturers intended to vastly increase the supply and use of addictive prescription opioids;
- admissions in the Manufacturers' files that document the success of their efforts through promotion to increase prescription opioid usage;
- public health and economic literature showing both that drug promotion increases sales and that ubiquitous access to opioids leads to widespread abuse;
- historical association between expanded access to addictive opioids and increased public health and social harms like those in the Plaintiff Counties;
- expert testimony by marketing and medical experts and a former FDA Commissioner that the Manufacturers created widespread misconceptions about opioid use, which breached fundamental requirements for delivery of prescription drug products in the United States that exist precisely to prevent the type of public health crisis that has emerged; and
- expert testimony by renowned public health economists that the Manufacturers' unlawful promotion led to sharply increased prescription opioid sales and shipments, which caused widespread public health and social harms related to both licit and illicit opioid use, which have and will continue to cost the Plaintiff Counties hundreds of millions of dollars to address.

The evidence that all Defendants' illegal failures to monitor for and block shipment of suspicious prescription orders likewise caused these harms and costs to the Plaintiff Counties includes:

- the fact that applicable Drug Enforcement Agency requirements to identify and prevent diversion had as their purpose the prevention of opioid abuse;
- admissions in the Defendants' files that these companies utterly failed, often intentionally, to comply with the DEA's requirements;
- the often-stated understanding by Defendants that, because of these failures, prescription opioids were being diverted to illicit use and causing harm;
- expert testimony by corporate compliance and pharmaceutical industry distribution standards experts that the Defendants utterly failed in their legal duty to establish and operate Suspicious Order Monitoring (SOM) systems;
- expert testimony by data analytics experts that the Defendants' SOM failures caused excess shipments of millions of suspicious orders of prescription opioids into the Plaintiff Counties; and
- expert testimony by the public health economists discussed above that the Defendants' SOM violations likewise caused sharply increased shipments, which caused the widespread public health and social harms related to both licit and illicit opioid use, which have and will continue to cost the Plaintiff Counties hundreds of millions of dollars to address.

Issue 2: Have Plaintiffs produced evidence that Defendants' rampant unlawful conduct was a legal or proximate cause of the extensive opioid-related harms Plaintiffs have suffered?

Answer: Yes. Legal or "proximate" turns on the foreseeability of a plaintiff's harms that resulted from a defendant's unlawful conduct. *BCS Services, Inc. v. Heartwood 88, LLC*, 637 F.3d 750, 758 (7th Cir. 2011); *City of Cincinnati v. Beretta U.S.A. Corp.*, 768 N.E.2d 1136, 1144 (Ohio 2002).

Here, the Plaintiff Counties demonstrate through much of the same evidence set forth above that the widespread public health and social harms they suffered were the direct and foreseeable results of the Defendants' unlawful promotion and failure to monitor for and block suspicious shipments of prescription opioids.

The evidence that these harms resulting from excess shipments were foreseeable to the Defendants includes:

- documents showing the Manufacturers' expectation of immense returns on investment through sharply increased sales from their many different forms of unlawful promotion practices;
- the well-established public health and economic literature showing both that drug promotion increases sales and that ubiquitous access to opioids leads to widespread abuse;

- Congress and the DEA’s recognition in enacting and enforcing the federal Controlled Substances Act that combatting diversion through a closed system of prescription drug distribution was necessary because illegal distribution of controlled substances has a substantial and detrimental effect on the public health and welfare; and
- the strong historical association between expanded access to addictive opioids and increased public health and social harms like those that emerged in the Plaintiff Counties.

Issue 3: May Plaintiffs rely upon statistical analysis of aggregate data as proof that the harms they suffered were caused by Defendants’ unlawful conduct?

Answer: Yes. Courts routinely allow parties to prove elements of their claims or defenses, including causation, using statistical analysis of aggregate evidence. *See, e.g., Tyson Foods, Inc. v. Bouaphakeo*, 136 S. Ct. 1036, 1046 (2016) (“A representative or statistical sample, like all evidence, is a means to establish or defend against liability.”); *In re Neurontin Mktg. & Sales Practs. Litig. (Kaiser)*, 712 F.3d 21, 42 (1st Cir. 2013) (“[C]ourts have long permitted parties to use statistical data to establish causal relationships.”); *Paige v. Calif.*, 291 F.3d 1141, 1148 (9th Cir. 2002) (“[I]t is a generally accepted principle that aggregated statistical data may be used where it is more probative than subdivided data.”); *U.S. ex rel. Martin v. Life Care Ctrs. of Am., Inc.*, 114 F. Supp. 3d 549, 560 (M.D. Tenn. 2014) (“[C]ourts now consider mathematical and statistical methods to be well recognized as reliable and acceptable evidence in determining adjudicative facts.”).

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